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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/686,522	10/11/2000	Rebecca E. Cahoon	BB1165 USNA	5214

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WILMINGTON, DE 19805

EXAMINER
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EINSMANN, JULIET CAROLINE

ART UNIT	PAPER NUMBER
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1634

DATE MAILED: 01/30/2003

17

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

09/686,522

Applicant(s)

CAHOON ET AL.

Examiner

Juliet C Einsmann

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 27 September 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 32-36, 43-46 and 48-51 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 32-36, 43-46, and 48-51 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☒ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

## Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_.
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 3 and 4. 6) ☐ Other: \_\_\_\_\_.

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### **DETAILED ACTION**

#### ***Continued Examination Under 37 CFR 1.114***

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after allowance or after an Office action under *Ex Parte Quayle*, 25 USPQ 74, 453 O.G. 213 (Comm'r Pat. 1935). Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, prosecution in this application has been reopened pursuant to 37 CFR 1.114.

Applicant's submission filed on 27 September 2002 has been entered.

2. Copies of the signed 1449's requested by applicant in paper number 14 are enclosed with this office action.

3. The indication of allowability of the pending claims is hereby WITHDRAWN in light of the new rejections set forth herein. Claims 32-36 and 43-51 are pending. The original numbering of the claims will be used for further prosecution.

4. The new sequence listings filed with the RCE have been added to the specification and to the PTO computer database.

#### ***Inventorship***

5. In view of the papers filed 4/9/02, the inventorship in this nonprovisional application has been changed by the deletion of Catherine J. Thorpe and William D. Hitz.

The application will be forwarded to the Office of Initial Patent Examination (OIPE) for issuance of a corrected filing receipt, and correction of the file jacket and PTO PALM data to reflect the inventorship as corrected.

***Oath/Declaration***

6. The oath or declaration is defective. A new oath or declaration in compliance with 37 CFR 1.67(a) identifying this application by application number and filing date is required. See MPEP §§ 602.01 and 602.02.

The oath or declaration is defective because:

The specification to which the oath or declaration is directed has not been adequately identified. See MPEP § 601.01(a). No box is checked to indicate whether the application was attached to the Declaration or was previously filed, although the information in the section regarding a previously filed application is set forth.

It does not identify the city and either state or foreign country of residence of each inventor. The residence information may be provided on either on an application data sheet or supplemental oath or declaration.

7. It is noted that the declaration is titled as a declaration in an application using an application data sheet. However, there is no application data sheet in the file. Clarification is required.

***Claim Objections***

8. Claim 46 is objected to because of the following informalities:

Claim 46 is improper because it is a product claim that depends from a method claim. In order to be properly dependent, a claim must incorporate all of the limitations of the previous claims, yet it is not clear how a product can incorporate all of the limitations of the method. Amendment of claim 46 to recite, for example, "A cell transformed with the polynucleotide of claim 32" would overcome this objection. Appropriate correction is required.

***Claim Rejections - 35 USC § 101***

9. 35 U.S.C. 101 reads as follows:

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Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

10. Claims 32-36, 43-46, and 48-51 are rejected under 35 U.S.C. 101 because the claimed invention is not supported by either a specific, substantial and credible asserted utility or a well established utility.

The sole independent claim in this claim set is drawn to isolated nucleic acids encoding a peptide having extragenic suppressor activity, wherein the amino acid sequence of the polypeptide and the amino acid sequence of SEQ ID NO: 14 have at least 80% homology. Further claims limit the scope of the claimed nucleic acid to encoding polypeptides 90% or 95% homology to SEQ ID NO: 14, or to encoding SEQ ID NO: 14 itself, or wherein the polynucleotide itself is instant SEQ ID NO: 13. The rejected claims also include claims to chimeric genes, vectors, host cells, transgenic plants and plant parts, methods of producing and isolating polypeptides and methods of making transgenic plants.

The specification asserts that the nucleic acid fragments and proteins of the instant invention may be used to isolate cDNAs and genes encoding homologous proteins using hybridization or amplification methods (p. 11-12), in immunological screening assays (p. 12), to create transgenic plants (p. 12), to express the encoded polypeptide (p. 13). These utilities are not specific utilities because they are applicable to a general class of molecules, that is to say all nucleic acids encoding polypeptides can be used in these types of methods.

The specification on page 13 refers to “the instant phytic acid biosynthetic enzymes,” and thus suggests that the instantly claimed polynucleotides can be used to alter phytic acid biosynthesis in transgenic plants. This is not considered a substantial utility because there is no evidence of record to support this utility. The specification teaches that instant SEQ ID NO: 14

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is 28% similar to an extragenic suppressor protein from cyanobacterium *Synechocystis*, citing the disclosure of Kaneko et al. (1996, DNA Research). However, this evidence is not sufficient to assign instant SEQ ID NO: 14 the functionality of an extragenic suppressor or to suggest that this protein is a phytic acid biosynthetic enzyme. First, the assignment of the *Synechocystis* protein as an extragenic suppressor is based on the fact that it has a 23.9% query match with the extragenic suppressor SuhB (See Table 1, page 122, fourth entry from the bottom). Thus, the instant assignment of SEQ ID NO: 14 as an extragenic suppressor is based on 30% identity to a sequence that has 24% identity to a sequence that is an extragenic suppressor. This is not sufficient evidence to conclude that instant SEQ ID NO: 14 is in fact an extragenic suppressor because the relationship between instant SEQ ID NO: 14 and the confirmed extragenic suppressor is so far removed. Second, neither the instant specification nor Kaneko et al. demonstrate that instant SEQ ID NO: 14 is involved in the phytic acid pathway. Kaneko et al. do not suggest that there is active in the phytic acid pathway. Furthermore, Kaneko et al. specifically state "It should be borne in mind, however, that the ORFs assigned in this paper merely represent the coding potentiality under the defined assumptions, and the real ORF should be validated experimentally (p. 111)."

Furthermore, even if it were established that SEQ ID NO: 14 is an extragenic suppressor, this is not sufficient to establish a specific or substantial utility, absent any guidance as to what the polypeptide suppresses, under what conditions the suppression takes place and to what effect. There is no specific guidance as to how to use the claimed extragenic suppressors, or what effect they may have on transformed organisms, for example the transgenic plants claimed herein. The term "polypeptide having extragenic suppressor activity" encompasses any polypeptide that has

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the ability to suppress any other gene. A wide variety of such molecules are known in the art (see for example Hong et al., Peng et al., and Vaidya et al.), but there is no correlation between a common structure or function of such molecules known. In order to determine if in fact SEQ ID NO: 14 is a polypeptide with extragenic suppressor activity, and if so, what gene it has the ability to suppress, and further still the real world utility for such an activity, further experimentation would be required. Thus, the instant claims lack a substantial utility because further experimentation would be required to reasonably confirm a real world utility for the claimed polynucleotides and constructs comprising them.

Claims 32-36, 43-46, and 48-51 are also rejected under 35 U.S.C. § 112, first paragraph. Specifically, since the claimed invention is not supported by a specific, substantial, and credible utility or a well-established utility for the reasons set forth above, one skilled in the art would not know how to use the claimed invention. For all the above reasons, the disclosure is insufficient to teach one of skill in the art how to use the invention. A review of *In re Wands*, 8 USPQ2d 1400 (CAFC 1988) clearly points out the factors to be considered in determining whether a disclosure would require undue experimentation and include (1) the quantity of experimentation necessary, (2) the amount of direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art and, (8) the breadth of the claims. All of these factors are considerations when determining the whether undue experimentation would be required to use the claimed invention. As is evidence in the discussions *supra*, each of these factors has been carefully considered in the instant grounds of

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rejection, and it is maintained that undue experimentation would be required by the skilled artisan to use the instant invention.

***Claim Rejections - 35 USC § 112***

11. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

12. Claims 32-34, 43-46, and 48-51 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The sole independent claim in this claim set is drawn to isolated nucleic acids encoding a peptide having extragenic suppressor activity, wherein the amino acid sequence of the polypeptide and the amino acid sequence of SEQ ID NO: 14 have at least 80% homology. Further claims limit the scope of the claimed nucleic acid to encoding polypeptides 90% or 95% homology to SEQ ID NO: 14. The rejected claims also include claims to chimeric genes, vectors, host cells, transgenic plants and plant parts, methods of producing and isolating polypeptides and methods of making transgenic plants. The claims thus encompass any polynucleotides encoding polypeptides having a particular percent identity to instant SEQ ID NO: 14 that also have extragenic suppressor activity. This large genus is represented in the specification by one species, namely, SEQ ID NO: 13. Thus, applicant has express possession of only one species in a genus which comprises hundreds of thousands of different possibilities.



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The claims recite that all of the encompassed polynucleotides must encode polypeptides having "extragenic suppressor activity," yet the specification does not define such activity by indicating what genes are suppressed by the activity of the polypeptides encoded by the claimed polypeptides. The specification does not even provide this information for the single disclosed putative extragenic suppressor activity. There is not disclosure in the prior art or the specification of a known structural features that can be used to identify the proteins within the claimed genus that in fact demonstrate the "extragenic suppressor activity." Thus, even though the claims recite a structure/function relationship, they are still rejected as lacking adequate written description because there is a lack of guidance as to how to select polynucleotide that do in fact encode extragenic suppressor proteins from within the genus disclosed in the claims, especially in light of the fact that it is not clear if in fact SEQ ID NO: 14 actually possesses extragenic suppressor activity.

It is noted that in Fiers v. Sugano (25 USPQ2d, 1601), the Fed. Cir. concluded that

"...if inventor is unable to envision detailed chemical structure of DNA sequence coding for specific protein, as well as method of obtaining it, then conception is not achieved until reduction to practice has occurred, that is, until after gene has been isolated...conception of any chemical substance, requires definition of that substance other than by its functional utility."

In the instant application, only the polynucleotide sequence of the SEQ ID NO: 13 or encoding SEQ ID NO: 14 are described. Also, in Vas-Cath Inc. v. Mahurkar (19 USPQ2d 1111, CAFC 1991), it was concluded that:

"...applicant must also convey, with reasonable clarity to those skilled in art, that applicant, as of filing date sought, was in possession of invention, with invention being, for purposes of "written description" inquiry, whatever is presently claimed."

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In the application at the time of filing, there is no record or description which would demonstrate possession of any nucleic acids modified by addition, insertion, deletion, substitution or inversion with the disclosed SEQ ID No: 13 but possessing one or more nucleic acid differences such that a different nucleic acid sequence encodes a protein that retains activity that is extragenic suppressor activity or that is the same as the activity of SEQ ID NO: 14.


***Conclusion***

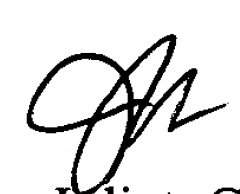
13. No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Juliet C. Einsmann whose telephone number is (703) 306-5824. The examiner can normally be reached on Monday through Friday, from 9:00 AM until 4:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, W. Gary Jones can be reached on (703) 308-1152. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-4242 and (703) 305-3014.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

  
W. Gary Jones  
Supervisory Patent Examiner  
Technology Center 1600

  
Juliet C. Einsmann  
Examiner  
Art Unit 1634

January 23, 2003